DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our Reference Nos: 93-0116 and 93-0142

JAN 18 1996

George R. Siber, M.D.
Massachusetts Public Health Biologic Laboratories
305 South Street
Boston, MA 02130

Dear Dr. Siber:

Enclosed is a product license authorizing Massachusetts Public Health Biologic Laboratories, U.S. License No. 64, to manufacture and ship Respiratory Syncytial Virus Immune Globulin Intravenous (Human), [RSVIGIV], for sale, barter, or exchange.

Under this license you are authorized to manufacture and prepare for shipment and sale, Respiratory Syncytial Virus Immune Globulin Intravenous (Human) for prevention of serious lower respiratory tract infection caused by Respiratory Syncytial Virus in children less than 24 months of age with bronchopulmonary dysplasia or a history of prematurity (less than or equal to 35 weeks gestation).

The product will be presented in 50 mL single-dose vials.

You are requested to submit samples of each future lot of the product in final containers together with protocols showing results of all applicable tests. No lots of product shall be distributed until notification of release is received from the Director, Center for Biologics Evaluation and Research.

The dating period for this product shall be 24 months from the date of manufacture when stored at 2-8 °C. The date of manufacture shall be defined as the date of the first sterile filtration of the final bulk. Please provide summaries of the stability results annually.

We note the commitment in your letter of December 21, 1995, to conduct a post-marketing study to further define the efficacy of Respiratory Syncytial Virus Immune Globulin Intravenous (Human) in children < 24 months of age with bronchopulmonary dysplasia or a history of premature birth (≤ 35 weeks gestation) and who weigh less than 5 kg at the commencement of the RSV season. We also note the commitment in your letter of January 4, 1996, to submit the results of the study to the Food and Drug Administration.

We will accept the abbreviated environmental assessment at this time, but retain the authority to request the omitted information at a future date.

Also, the supplement to your establishment license application (Reference No. 93-0116) to provide for the manufacture of Respiratory Syncytial Virus Immune Globulin Intravenous (Human) has been approved.

The information contained in the establishment supplement will be included in your establishment license application file.

Any changes in the manufacture, testing, packaging or labeling of the product or in the manufacturing facilities may require the submission of a supplement to either your product or establishment license application for our review and written approval prior to implementation.

In addition, please submit three copies of the introductory advertising and promotional labeling. You may wish to submit the proposed materials in draft form with an FDA form 2567 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Staff, HFM-202, 1401 Rockville Pike, Rockville, MD 20852-1448. Promotional claims should be consistent with and not contrary to approved labeling. No comparative claims or claim of superiority over other similar products should be made unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research.

It is requested that adverse experience reports be submitted in accordance with the requirements for postmarketing reporting of adverse experiences for licensed biological products (21 CFR 600.80) and that distribution reports be submitted as described (21 CFR 600.81). All experience reports should be prominently labeled as outlined in 21 CFR 600.80 and be submitted to the Center for Biologics Evaluation and Research (HFM-210), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448.

A review of labeling has been sent under separate cover. Please submit three copies of final printed labeling at the time of use and include part II of the label transmittal form with completed implementation information.

Please acknowledge receipt of the enclosed product license to the Director, Division of Blood Applications, HFM-370, Center for Biologics Evaluation and Research.

Sincerely yours,

Jay S. Epstein, M.D.
Director
Office of Blood Research and Review
Center for Biologics
Evaluation and Research

Jerome A. Donlon, M.D., Ph.D.
Director
Office of Establishment Licensing
and Product Surveillance
Center for Biologics
Evaluation and Research